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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,122	11/13/2003	John D. Pluenncke	3369-A	7679

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IMMUNEX CORPORATION
PATENT OPERATIONS/MS 28-2-C
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320-1799

EXAMINER

DELACROIX MUIRHE, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,122

Applicant(s)

PLUENNEKE, JOHN D.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The following is responsive to applicant's amendment and remarks received Nov. 14, 2005.

New claims 8-17 are added. Claims 1-17 are currently pending.

Upon further consideration of the claims and specification, the examiner respectfully submits the following supplemental restriction requirement below. The previous requirement mailed Oct. 12, 2005 is withdrawn.

Due to the complex nature of the claims, no request for an oral election is being made. Please see MPEP 812.01.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 8-17 drawn to a method for reducing tumor burden, classified in class 514, subclass 2+.
- II. Claims 3-4, drawn to a method for inhibiting recurrence of gross cystic disease of the breast, classified in class 514, subclass 2+.
- III. Claims 5-7, drawn to a method for preventing or reducing the frequency or severity of transient ischemic attacks or strokes, classified in class 514, subclass 2+.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is directed to a method of reducing tumor burden in a human patient; the invention of Group II is directed to a method of inhibiting the recurrence of gross cystic disease of the breast; the invention of Group III is directed to a method of preventing or

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reducing the frequency or severity of transient ischemic attacks or strokes. Each method has a separate and distinct outcome from the expected outcome of any one or more of the other methods. For example, the expected result of a method of treating tumor burden is distinctly different from a method of reducing the frequency or severity of ischemic attacks strokes, since the desired outcome of reducing tumor burden is to arrest abnormal proliferation and metastatic spread of tumor cells, whereas the desired outcome of treating ischemic attacks or strokes is to reduce the likelihood of an ischemic attack in a patient suffering from, for example, hypertension.

Additionally, each of the methods would be practiced in a distinctly different population of patients. While there may be incidental overlap in the groups of patients experiencing, for example, cancer and those experiencing, for example, strokes or gross cystic disease of the breast, the therapeutic objective, endpoints and steps required to treat such dissimilar conditions are vastly different and do not reasonably suggest the treatment of the other. Finally, the search for one Group would not be required for the other. For these reasons, the inventions of Groups I-III are considered to be independent and distinct and restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 1, 3, 5 are generic to the following disclosed patentably distinct species of EGFR inhibitors described on pages 13-19 of the specification. Examination of the generic claims in Groups I - III in their entirety would constitute an undue burden on the Examiner. The distinct

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nature of the species above is supported by the fact that each compound has a different structure/chemistry. Such is sufficient to indicate that each compound listed above is differently searched in the patent and non-patent literature and that a search for one compound will not necessarily result in a comprehensive search of any one or more of the other compounds listed. Despite the fact that applicant may have established an underlying commonality for the claimed compounds, i.e. inhibitors of EGFR, it remains that each of the compounds is recognized in the art as being chemically and structurally distinct from one another and, thus, each of the above-identified species is capable of supporting separate patents.

Upon election of either Group I or II or III, applicant must further elect a species of EGFR inhibitor, for example, tyrosine kinase inhibitor ZD-1839 (page 18, line 28).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

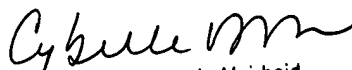
you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM



Feb. 17, 2006



Cybille Delacroix-Muirheid
Patent Examiner Group 1600